United States District Court

EASTERN DISTRICT OF TEXAS TYLER DIVISION

ALLERGAN, INC.	§	
	§	
v.	§	Cause No. 6:11-cv-441
	§	Consolidated Case
SANDOZ INC., ET AL.	§	6:11CV611
•		6:12CV043
		6.1201107

FINAL JUDGMENT AND PERMANENT INJUNCTION

In accordance with Federal Rule of Civil Procedure 58, the Court enters the following final judgment.

A bench trial was held in the above-styled case from July 15–19, 2013. Consistent with the Court's contemporaneously filed Findings of Fact and Conclusions of Law, it is **ORDERED** that:

- 1. Allegan Inc. ("Allergan") asserted the following claims against Sandoz Inc. ("Sandoz"); Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin"); Hi-Tech Pharmacal Co., Inc. ("Hi-Tech"); and Watson Laboratories Inc., Watson Pharmaceuticals, Inc. and Watson Pharma Inc. ("Watson"): claim 2 of the '504 patent; claims 1, 7, and 8 of the '353 patent; claim 15 of the '479 patent; claims 1, 7, and 8 of the '118 patent; and claims 1, 6, 10, and 12 of the '605 patent (the "asserted claims").
- 2. PURSUANT TO 35 U.S.C. § 271(e), 28 U.S.C. §§ 2201 and 2202, the COURT ENTERS JUDGMENT THAT Sandoz's proposed products described in Abbreviated New Drug Application ("ANDA") No. 203056, and the COMMERCIAL USE, SALE, OFFER FOR SALE, MANUFACTURE AND IMPORTATION of those products, WILL AND DO directly and indirectly infringe the asserted claims of the patents-in-suit pursuant to 35 U.S.C. §§ 271(a), (b), (c) and (e).

- 3. PURSUANT TO 35 U.S.C. § 271(e) 28 U.S.C. §§ 2201 and 2202, the COURT ENTERS JUDGMENT THAT Lupin's proposed products described in Abbreviated New Drug Application ("ANDA") No. 202911, and the COMMERCIAL USE, SALE, OFFER FOR SALE, MANUFACTURE AND IMPORTATION of those products, WILL AND DO directly and indirectly infringe the asserted claims of the patents-in-suit pursuant to 35 U.S.C. §§ 271(a), (b), (c) and (e).
- 4. PURSUANT TO 35 U.S.C. § 271(e), 28 U.S.C. §§ 2201 and 2202, the COURT ENTERS JUDGMENT THAT Hi- Tech's proposed products described in Abbreviated New Drug Application ("ANDA") No. 203604, and the COMMERCIAL USE, SALE, OFFER FOR SALE, MANUFACTURE AND IMPORTATION of those products, WILL AND DO directly and indirectly infringe the asserted claims of the patents-in-suit pursuant to 35 U.S.C. §§ 271(a), (b), (c) and (e).
- 5. PURSUANT TO 35 U.S.C. § 271(e), 28 U.S.C. §§ 2201 and 2202, the COURT ENTERS JUDGMENT THAT Watson's proposed products described in Abbreviated New Drug Application ("ANDA") No. 203748, and the COMMERCIAL USE, SALE, OFFER FOR SALE, MANUFACTURE AND IMPORTATION of those products, WILL AND DO directly and indirectly infringe the asserted claims of the patents-in-suit pursuant to 35 U.S.C. §§ 271(a), (b), (c) and (e).
- 6. The asserted claims are not invalid. The asserted claims are not unenforceable.
- 7. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of any of the drugs described in Sandoz's ANDA No. 203056 will be a date that is not earlier than the date of the expiration of all of U.S. Patent Nos. 7,851,504; 8,278,353; 8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.

- 8. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of any of the drugs described in Lupin's ANDA No. 202911 will be a date that is not earlier than the date of the expiration of all of U.S. Patent Nos. 7,851,504; 8,278,353; 8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.
- 9. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of any of the drugs described in Hi-Tech's ANDA No. 203604, will be a date that is not earlier than the date of the expiration of all of U.S. Patent Nos. 7,851,504; 8,278,353; 8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.
- 10. Pursuant to 35 U.S.C. §§ 271(e)(4)(A) and 283, the effective date of any FDA approval of any of the drugs described in Watson's ANDA No. 203748 will be a date that is not earlier than the date of the expiration of all of U.S. Patent Nos. 7,851,504; 8,278,353; 8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.
- 11. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, Sandoz Inc., including any of its subsidiaries, successors, assigns, officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any or all of them ("Sandoz"), and any persons in privity with Sandoz, and any person or entity to whom Sandoz transfers Abbreviated New Drug Application No. 203056 are enjoined from the commercial manufacture, use, offer to sell and/or sale of the products described in Sandoz's Abbreviated New Drug Application No. 203056 within the United States and its territories or importing the described products into the United States and its territories until after the latest of the expiration dates of U.S. Patent Nos. 7,851,504; 8,278,353; 8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.

- 12. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, Lupin Ltd. and Lupin Pharmaceuticals, Inc., including any of their subsidiaries, successors, assigns, officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any or all of them ("Lupin"), and any persons in privity with Lupin, and any person or entity to whom Lupin transfers Abbreviated New Drug Application No. 202911 are enjoined from the commercial manufacture, use, offer to sell and/or sale of the products described in Lupin's Abbreviated New Drug Application No. 202911 within the United States and its territories or importing the described products into the United States and its territories until after the latest of the expiration dates of U.S. Patent Nos. 7,851,504; 8,278,353; 8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.
- 13. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, Hi-Tech Pharmacal Co., Inc., including any of its subsidiaries, successors, assigns, officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any or all of them ("Hi-Tech"), and any persons in privity with Hi-Tech, and any person or entity to whom Hi-Tech transfers Abbreviated New Drug Application No. 203604 are enjoined from the commercial manufacture, use, offer to sell and/or sale of the products described in Hi-Tech's Abbreviated New Drug Application No. 203604 within the United States and its territories or importing the described products into the United States and its territories until after the latest of the expiration dates of U.S. Patent Nos. 7,851,504; 8,278,353; 8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.
- 14. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, Watson Laboratories Inc., Watson Pharmaceuticals, Inc. and Watson Pharma Inc., including any of their subsidiaries, successors, assigns, officers, agents, servants, employees, and attorneys, and those

persons in active concert or participation with any or all of them ("Watson"), and any

persons in privity with Watson, and any person or entity to whom Watson transfers

Abbreviated New Drug Application No. 203748 are enjoined from the commercial

manufacture, use, offer to sell and/or sale of the products described in Watson's

Abbreviated New Drug Application No. 203748 within the United States and its

territories or importing the described products into the United States and its territories

until after the latest of the expiration dates of U.S. Patent Nos. 7,851,504; 8,278,353;

8,299,118; 8,309,605; and 8,338,479, plus any exclusivities afforded under the statute.

15. Judgment is entered in favor of Plaintiffs and against Defendants on all counterclaims.

16. Allergan is the prevailing party, and costs are awarded to Allergan.

It is additionally ORDERED, ADJUDGED, and DECREED that final judgment be

entered in this case.

All relief not previously granted is hereby **DENIED**.

It is SO ORDERED.

SIGNED this 13th day of January, 2014.

UNITED STATES DISTRICT JUDGE

had Ukhnila